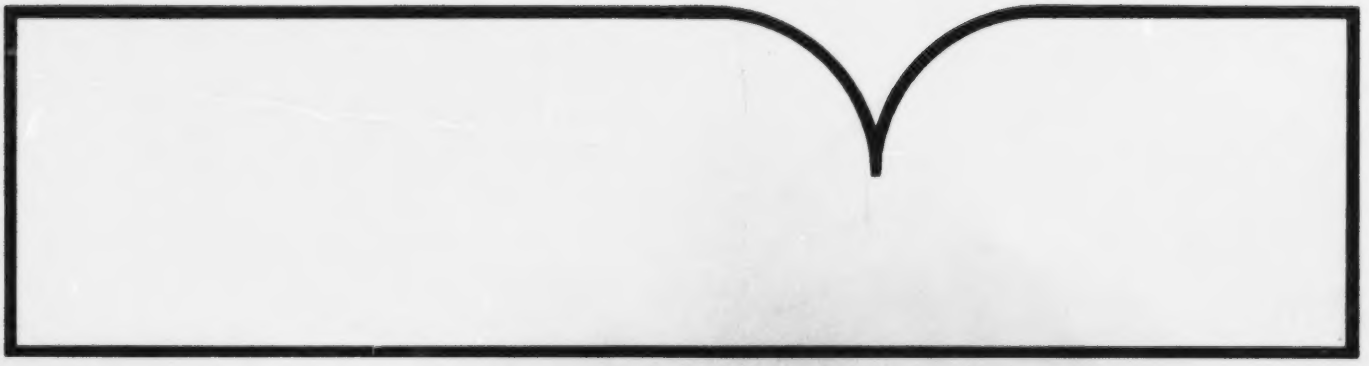
PB80-226418

Isocyanurate 3(c)(2)(B) Letter

(U.S.) Environmental Protection Agency
Arlington, VA

26 Mar 80



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401 M St. S.W.
Washington, D.C. 20460

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3(c)(2)(B) Letter:

A 3(c)(2)(B) letter is notification under Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act that the U.S. Environmental Protection Agency has determined that additional data are required to maintain registrations of products containing chemicals under Agency review. Companies must generate and submit data to EPA within scheduled timeframes to maintain registration. The notice lists what data are needed, gives schedules for submitting data, and procedures for requesting waivers and extensions of time.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA/SPRD-80/100

MAR 26 1980

OFFICE OF TOXIC SUBSTANCES

Dear Registrant

Our records indicate that you are the registrant of one or more of the following active ingredients which we will refer to as isocyanurates:

1. Dichloro-s-triazinetrione
2. s-Triazinetriol
3. Potassium dichloro-s-triazinetrione
4. Sodium dichloro-s-triazinetrione
5. Trichloro-s-triazinetrione
6. (Mono(trichloro)tetra(monopotassium dichloro),penta-s-triazinetrione

A list of your products that contain any of these materials is shown as Appendix A.

I. REQUIREMENT FOR DATA SUBMISSION

Under the authority of Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), EPA has determined that additional data, more fully described in Section II of this letter, are required to maintain in effect these registrations.

This letter notifies you, as required by FIFRA Section 3(c)(2)(B), that you are obliged to take steps to generate (if necessary) and submit data to EPA, in accordance with the schedule set forth in Section III of this letter, if you wish your registration to be maintained in effect.

Sections IV and V of this letter indicate two limited circumstances in which EPA will not act to suspend the registration of your products if you do not submit the required data. Section VI of this letter describes the procedures by which you may ask EPA to reconsider the requirements imposed by this letter.

In responding to the data requirements established by this letter, you must choose one of the following options:

(A) You must notify EPA within 90 days of your receipt of this letter that you are willing to generate (if necessary) and submit the data yourself;

(B) You must notify EPA within 90 days of your receipt of this letter that you have entered into an agreement, with one or more of the other registrants who are subject to this notice's requirement, to jointly generate (if necessary) and submit the data, or to share in the cost of this work;

(C) You must file with EPA, within 30 days of your receipt of this letter, a request for a waiver of some or all of the data requirements imposed by this Order and Notice.

(D) You must provide to EPA, within 30 days of your receipt of this letter, the Certification described in Section IV of this letter, which will allow EPA to exempt you from the consequence of not submitting some or all of these data because each of your products is an end-use product and otherwise qualifies under that Section; or

(E) You must file with EPA, within 90 days of your receipt of this letter, a request that the registration for all of your isocyanurate-containing products be voluntarily cancelled.

If you fail to exercise one of these options within the time period specified, EPA may take steps to suspend the registration of each product to which the required data are pertinent.

II. WHAT DATA ARE NEEDED

EPA has determined that it lacks adequate data to determine whether pesticide products containing an isocyanurate cause unreasonable adverse effects on the environment. These products are used for a variety of pesticidal purposes including control of bacteria in swimming pools and cooling towers on food contact surfaces, and fabrics, such as diapers.

Virtually all of the chronic toxicity tests supporting the registration of products containing chlorinated isocyanurate were performed by Industrial Bio-Test Laboratories ("IBT"). The Agency has reviewed those studies and determined that the resulting data are not sufficient to support the continued registration of these products.

Because a large number of people are exposed to isocyanurate products, primarily as a result of their use in swimming pools, EPA has determined that it is necessary to obtain reliable data on the toxic effects of and degree of human exposure to these pesticides. This conclusion is reinforced by indications in the IBT studies and other studies that isocyanurate may cause damage to kidneys.

In addition, the Agency has reviewed the existing product chemistry data on the isocyanurate products and has determined that the existing information is inadquate to establish the nature and content of the registered products or the applicability of the safety data.

The Agency is also concerned about the potential environmental impact of the use of isocyanurate products and has decided to use a tiered approach to developing the data. At this time the environmental concerns will be addressed by studies designed to characterize and quantify the environmental contamination with isocyanurate. Based on this information an assessment will be made of the need for further environmental fate and ecological effects data.

The Agency has determined that data from the types of studies listed below are required to support the registration of all products containing isocyanurate. The required data must be submitted and any necessary studies must be conducted in accordance with the referenced sections of EPA's proposed pesticide registration sections of EPA's proposed pesticide registration guidelines, */ except as modified or supplemented below. **/

*/ The pesticide registration guidelines were proposed in three separate publications. On July 10, 1978 EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336. The product chemistry references are to the 9/27/79 draft of guidelines for Registering Pesticides in the United States: Subpart D Chemistry Requirements: Product Chemistry. Copies are available on request.

**/ Note: you may request EPA to approve the use of a test method which does not satisfy the test standards listed above in order to generate the required data. The procedures for submitting such a request are described in Section VI of this letter.

PRODUCT CHEMISTRY DATA

Compound to be Tested

For product chemistry, separate data are needed for each manufacturing use product or formulated product produced by an integrated formulation system. Our review of the existing registrant submitted data on product chemistry has shown that only a very small percentage of the requirements for each chemical have been met and that the information which has been submitted has not necessarily been up-dated to include all currently available data. Therefore the following statement of the data requirements applies equally to each of the chemicals in the isocyanurate group. This information must be submitted independently by each registrant in the group since it is used to confirm the nature of the actual product and thus the applicability of the available safety data.

Product Chemistry Data Requirements:

	Reference in Draft Guidelines
(1) For manufacturing-use products	
Product identity	163.61-3(a)
Confidential statement of formula	163.61-3(b)
Identification of ingredients	163.61-3(c)
Identification of technical chemical	163.61-3(d)
Manufacturing process	163.61-4
Formation of ingredients	163.61-5
Sample analysis	163.61-6(b)
Certification of limits	163.61-8(a),(b)
Analytical methods	163.61-9(a),(b)(1)
Physical and chemical properties	163.61-10
Submittal of samples	163.61-11
(2) Formulated products produced by an integrated formulation system	
Product identity	163.61-3(a)
Confidential statement of formula	163.61-3(b)
Identification of ingredients	163.61-3(c)
Identification of technical chemical	163.61-3(d)
Manufacturing process	163.61-4
Formation of ingredients	163.61-5
Sample analysis	163.61-6(c)
Certification of limits	163.61-8(a),(c)
Analytical methods	163.61-9(a),(b)(2)
Physical and chemical properties	163.61-10
Submittal of samples	163.61-11

TOXICOLOGY DATA

The following paragraphs contain certain requirements pertaining to the conduct of studies to generate the data required by this letter. These paragraphs may modify, supplement, or supersede certain of the test standards contained in the referenced sections of the pesticide guidelines. When performing studies to generate the required data, you should be very careful to follow every applicable test standard contained either in the guidelines or in the paragraphs below.

Compound to be Tested

All six active ingredients in the isocyanurate group break down into cyanurate ions, and chlorine and/or other chemicals. EPA is concerned with characterizing the toxicity of the cyanurate ion, since the toxicity of the other breakdown products is well establised. Recognizing that the presence of chlorine in water can make the water unpotable for different test species, EPA has decided to require testing with the sodium salt of cyanuric acid. Testing with sodium cyanurate will produce data which indicate the direct toxicity of the cyanurate ion rather than the effects of an animal's refusal to drink water containing high concentrations of chlorine.

Data requirements specified for toxicology apply to all registrants of any of the chemicals in the isocyanurate group. All data requirements specified in this section relate to the technical chemical or manufacturing-use products rather than formulated end-use products.

1. Subchronic Oral Dosing - Rat: proposed Section 163.82-1, 43 FR 3736-66 modified as follows: The highest dose should be the maximum permitted by the solubility of sodium cyanurate. The material should be administered in drinking water. An additional 40 animals should be used in the high dosage and controls to permit 8 animals to be sacrificed every two weeks in order to follow the development of any kidney toxicity.

2. Subchronic Oral Dosing - Dog: proposed Section 163.82-1, 43 FR 3736-66 modified as follows: A preliminary study should be undertaken to determine if it is feasible to administer sodium cyanurate in drinking water. If it is feasible to administer sodium cyanurate in drinking water, the high dose should be the maximum permitted by its solubility and lower doses should be appropriate fractions thereof. If administration in drinking water is not feasible the registrant should suggest another method of oral administration.

3. Subchronic 90-Day Dermal Toxicity Study: proposed Section 163.82-3, 43 FR 37368-70 modified as follows: Exposure is to be to a water solution of sodium cyanurate. The highest dose level administered shall be the maximum which is soluble in water.

4. Chronic Feeding Study: proposed Section 163.83-1, 43 FR 37375-79 modified as follows: The material shall be administered in drinking water.

5. Oncogenicity Studies: proposed Section 163.83-2, 43 FR 37379-82, modified as follows: The material shall be administered in drinking water.

6. Teratogenicity Studies: proposed Section 163.83-3, 43 FR 37382-84.

7. Reproduction Studies: proposed Section 163.83-4, 43 FR 37384-88.

8. Mutagenicity Studies: proposed Section 163.84-1 through 163.84-4, 43 FR 37388-94.

9. General Metabolism Study - Rat: proposed Section 163.85-1 43 FR 37394-96, modified as follows: The blood kinetics portion of the study is not required.

10. General Metabolism Study - Dog: proposed Section 163.85-1 43 FR 37394-96 modified as follows: Test animal to be the dog, number of animals to be 2 per sex per test group. The study should include additional non-traumatic kidney function tests including inulin clearance, urine concentrating ability, and response to water load.

ENVIRONMENTAL FATE DATA

Compound to be Tested

The Agency has determined that the testing for environmental fate should be conducted using the same material as the toxicology studies (sodium cyanurate).

Environmental Fate Data Requirements

1. Hydrolysis: proposed 163.62-7(b) 43 FR 29717.

2. Photodegradation: proposed 163.62-7(c) 43 FR 29717

3. Swimming Pool Dissipation

Studies must be conducted to determine the fate of the cyanurate in treated pools. Such studies must establish cyanurate decline curves in treated pools both for pools in active use and for pools left untreated at the end of the swimming season. Tests shall be conducted to determine the mechanisms of dissipation and to identify and quantify the degradation products.

4. Survey of Swimming Pool Drainage Practices

In order to determine the potential for environmental contamination by cyanurate, the Agency requires a survey of swimming pool practices for cyanurate treated pools. The study must be designed to answer the following questions:

1. What different drainage practices are followed?
2. What are the regional differences in drainage practices?
3. What are the differences in drainage practices for municipal and residential pools?
4. Where are pools drained (i.e., on ground, storm drains, sewers)?
5. How frequently are pools drained?
6. What is the time lapse between last treatment and drainage?

EXPOSURE DATA

1. Concentration of Cyanurate in Swimming Pools

EPA needs information on the average and maximum concentrations of cyanurate present in swimming pools under various use conditions in order to determine actual human exposure. Water samples should be obtained from an appropriate number and type of swimming pools and analyzed for cyanurate. The pools sampled should represent a valid statistical sampling of the various types of swimming pool use patterns, such as public verses private pools and pools used year round verses pools used only during the summer. In addition, the impact of water chemistry (i.e. minerals/hardness/pH/organic contamination) and bather load on the concentration should be established. In each case the time and amount of the last treatment should be documented.

2. Survey of Swimming Practices

In order to establish the exposure of swimmers to isocyanurates the Agency requires a survey of current swimming practices.

The study must be designed to establish the distribution of frequency and duration of swimming in isocyanurate treated pools by age, sex, and geographical region.

III. SCHEDULE FOR SUBMITTING DATA

The required data must be submitted to the Agency on the following schedule.*/ If progress reports are required, the schedule will specify the date on which the first progress report is due, and the frequency of progress reports thereafter. If required, progress reports must be provided as specified below.*/

1. PRODUCT CHEMISTRY DATA

   Final report due 10/1/80

2. TOXICOLOGY DATA

   a. Subchronic Oral Dosing-Rat

      Final report due by 1/1/81

      Progress report due by 10/1/80

   b. Subchronic Oral Dosing - Dog

      Final report due by 4/1/81

      Progress report due by 10/1/80 and bimonthly thereafter.

   c. Subchronic 90-Day Dermal Toxicity Study

      Final report due by 1/1/81

      Progress report due by 10/1/80

   d. Chronic Feeding Study

      Final report due by 6/1/83

      Progress reports due on 1/1/81 and quarterly thereafter.

   e. Oncogenicity Studies

      Final report due on 1/1/83

      Progress reports due on 1/1/81 and quarterly thereafter.

*/ Note: You may request that EPA extend any of the following deadlines. The procedures for submitting such a request are described in Section VI of this letter.

f. Teratogenicity Studies

Final report due 1/1/81

g. Reproduction

Final report due 8/1/83

Progress reports due on 8/1/80 and quarterly thereafter.

h. Mutagenicity Studies --

(1) A statement by 8/1/80 of which kinds of mutagenicity data will be provided.

(2) If any of the following kinds of studies is performed:

(a) bacterial point mutation studies;

(b) eukaryotic micro-organism point mutation studies;

(c) mammalian somatic cells in culture point mutation study;

(d) DNA repair in bacteria;

(e) unscheduled DNA repair synthesis in mammalian cells;

(f) mitotic recombination and/or gene conversion in yeast;

(g) sister chromatid exchange in mammalian cells; --

Final report due by 10/1/80

(3) If any of the following kinds of studies is performed:

(a) sex linked recessive lethal test in insects;

(b) <u>in vivo</u> cytogenetics in mammals;

(c) insect tests for heritable chromosomal effects;

(d) dominant lethal effects in rodents;

(e) heritable translocation tests in rodents --

Final report due by 3/1/81

(4) If a mouse specific locus test is performed,

Final report is due by 1/1/82

i. General Metabolism Study --

Final report due by 1/1/81

j. Metabolism Study in Dogs --

Final report due by 1/1/81

3. ENVIRONMENTAL FATE DATA

a. Hydrolysis

Final report due by 2/1/81

b. Photodegradation

Final report due by 2/1/81

c. Swimming Pool Dissipation

Final report due by 2/1/81

d. Survey of Swimming Pool Drainage Practices

Final report due by 2/1/81

4. EXPOSURE DATA

a. concentration of cyanurate in swimming pools

Final report due by 2/1/81

b. survey of swimming pool practices

Final report Due 2/1/81

IV. EXEMPTION FROM SUSPENSION SANCTION FOR CERTAIN END-USE PRODUCT REGISTRATIONS

The data described in Section II of this letter all relate solely or primarily to the safety of the active ingredient rather than to the safety or efficacy of individual end-use products. Accordingly, if these data had already been submitted to EPA, an applicant for registration of an end-use product would not, by virtue of FIFRA Section 3(c)(2)(D), be required to submit, or pay compensation for, those data as a condition of obtaining registration if the isocyanurate would be present in his product solely as the result of his incorporation into his product, as part of the formulation or packaging, of another isocyanurate containing product which itself is registered under FIFRA and which he purchases from another producer. The object of this provision is to simplify data compensation by making compensation for data on active ingredient safety an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient's safety.

EPA has concluded that these principles should also apply in the closely analogous situation presented by this Section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the isocyanurate in his product is being purchased from a firm which does have a duty to submit (or to offer to share in the cost of obtaining) the data required by this letter.

If a registrant who is subject to this Section 3(c)(2)(B) Order and Notice fails to comply with the data submission requirement, the Administrator may suspend his registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if:

(1) The registration is for an end-use product, as opposed to a manufacturing-use product; and

(2) The isocyanurate in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of another isocyanurate-containing product which is registered under FIFRA and which is purchased by the registrant; and

(3) The registrant completes and executes a "Certification of Entitlement to Exemption from Suspension Under FIFRA Section 3(c)(2)(B)", in the form of Appendix B to this letter, for each of his registered isocyanurate-containing products, and submits it to EPA not later than May 2, 1980; and

(4) One or more registrants actually does undertake to submit, and does submit, all the data required by this Order and Notice.

V. EXEMPTION FROM SUSPENSION SANCTION FOR REGISTRANTS WHO OFFER TO SHARE IN THE EXPENSE OF OBTAINING DATA

FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compell any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements in this letter, or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could tie up testing facilities unnecessarily, and the additional costs that would be incurred would make duplication wasteful.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed us of its intent to develop and submit data required by this Notice and Order; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing (on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)); and (3) the first registrant has without good cause declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

The format for informing EPA of the bonafide offer to the first registrant is shown as Appendix C.

VI. PROCEDURES FOR REQUESTING WAIVERS, CHANGES IN TESTING METHODOLOGY, AND EXTENSIONS OF TIME

EPA recognizes that you may disagree with our conclusions regarding the need for data, the appropriate ways to develop the required data, and how quickly the data must be submitted. We will give you the opportunity to state the basis for your disagreement and the request that we change our requirements. We note that if you seek to challenge our requirements in court, a judge may dismiss your lawsuit unless you have first presented your arguments to EPA according to the procedures described below.*/

If you think that EPA does not need the data required by this letter to determine whether your product causes unreasonable adverse effects on the environment, you may request a waiver. The waiver request must be submitted within 30 days of your receipt of this letter. The waiver request must be submitted in writing to the person specified at the end of this letter. The waiver request should state the reasons why you conclude that each particular kind of data is not needed. EPA will promptly review your request and any others and inform you whether the waiver has been granted.

If you want to use, or think that you should use, a test methodology which does not satisfy the test standards specified in Section II of this letter, you may ask EPA to review and approve that methodology. The request must be submitted in writing to the person specified at the end of this letter.

In most cases, EPA will not grant an extension of time to submit required data on the ground that you have requested Agency approval to change the required test methodology. Accordingly, you should submit the request as soon as possible.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to person specified at the end of this letter. The extension request

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*/ This letter constitutes "final Agency action" unless a request for a waiver, a request for a modification in the required test methodology, or a request for extension of time has been submitted. If any such request has been submitted, EPA's action with regard to the subject matter of the request does not become final until the Agency has acted on the request. The Agency thinks that a registrant must use the procedures described in this section of the letter in order to exhaust its administrative remedies.

should state the reasons why you conclude that an extension is appropriate. No extensions will be granted based on the fact that the Agency is considering your request for an extension. Accordingly, you must continue to work diligently to meet the deadline for submitting the required data while EPA considers your request.

VII. CONCLUSION

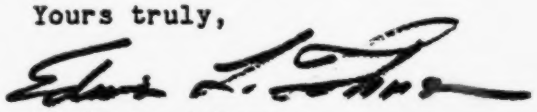
If you have any questions regarding the requirements and procedures established by this letter, please contact: Mike Branagan, Project Manager (703) 557-7400.

All responses to this notice should be submitted to:

Director, Special Pesticide Review Division (TS-791)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M St., S.W. Washington, D.C. 20460

ATTN: Isocyanurate Project Manager (1-2)

Yours truly,



Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs

APPENDIX B

EPA Product Registration Number: _____

Registrant's Name: _____

CERTIFICATION OF ENTITLEMENT TO EXEMPTION FROM SUSPENSION UNDER FIFRA Section 3(c)(2)(B)

As an authorized representative of the registrant of the product identified above, I hereby certify that:

(1) I have read and am familiar with the terms of a notice from EPA dated 3/26/80 concerning a requirement for submission of data under FIFRA Section 3(c)(2)(B) on an active ingredient in the class of isocyanurates.*/

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the ground that the product is an end-use product and it will contain an active ingredient in the class of chlorinated isocyanurates solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate confidential formula statement for the above-identified product, current as of the date of this Certification, is on file with EPA's Registration Division or attached to this certification. That formula statement indicates, by company name, registration number, and product name, the source of the chlorinated isocyanurate in my firm's product. My firm will apply for an amendment to the registration prior to changing the source of the isocyanurate in our product.

_____

*/ The class of isocyanurates includes the following six active ingredients:

1. Dichloro-s-triazinetrione
2. s-Triazinetriol
3. Potassium dichloro-s-triazinetrione
4. Sodium dichloro-s-triazinetrione
5. Trichloro-s-triazinetrione
6. (Mono(trichloro)tetra(monopotassium dichloro),penta-s-triazinetrione

(4) I understand, and agree on behalf of my firm, that if at any time any of the statements in this Certification are no longer true, or if my firm fails to comply with the undertakings made in this Certification, my firm's product's registration may be suspended in accordance with FIFRA Section 3(c)(2)(B).

Dated: _____

_____
Authorized representative of

Registrant's name:_____

Registrant's address_____

_____

APPENDIX C

STATEMENT OF WILLINGNESS TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA

(1) I am duly authorized to represent the following firm(s) who are subject to the requirement of an Order and Notice dated 3/26/80 under FIFRA Section 3(c)(2)(B), 7 U.S.C. Section 136a(c)(2)(B), to submit data concerning isocyanurate:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Order and Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement, which included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm:	Date of offer:

However, my firms's offer was not accepted by any of those firm(s).

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Order and Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registrations under FIFRA Section 3(c)(2)(B).

Dated: _____ _____

for: Firm(s)